


Exhibit E

 KeyCite Yellow Flag - Negative Treatment
Disagreement Recognized by *In re Processed Egg Products Antitrust Litigation*, E.D.Pa., November 12, 2015

2014 WL 4272018

NOT FOR PUBLICATION

United States District Court,

D. New Jersey.

Edward SCHWARTZ, on behalf of himself
and all others similarly situated, Plaintiff,

v.

AVIS RENT A CAR SYSTEM, LLC, and
Avis Budget Group, Inc., Defendants.

Civil Action No. 11-4052 (JLL).

|

Signed Aug. 28, 2014.

Attorneys and Law Firms

Jeffrey Alan Shooman, Bruce Daniel Greenberg, Lite
DePalma Greenberg, LLC, Newark, NJ, for Plaintiff.

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for Defendants.

OPINION

LINARES, District Judge.

*1 This matter comes before the Court by way of Plaintiff Edward Schwartz ("Plaintiff")'s, motion to certify class pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure, [CM/ECF No. 146],¹ and Defendants' motion to exclude Plaintiff's expert Dr. Vicki Morwitz's testimony [CM/ECF No. 149.] The Court has considered the submissions made in support of and in opposition to

Base Rate and Charges

Base Rate	\$94.99/day
Energy Recovery Fee	\$0.50/day
Vehicle License Fee	\$3.00/day
Customer Facility Fee	\$2.25/day
Concession Recovery Fee	10%

both motions. No oral argument was heard pursuant to Federal Rule of Civil Procedure 78. For the reasons that follow, Defendants' motion to exclude Plaintiff's expert testimony is denied and Plaintiff's motion to certify is granted.

I. BACKGROUND

As the Court writes only for the parties, it will set forth only those facts it deems relevant to deciding Defendant's motion.

Plaintiff brings this action on behalf of himself and a putative class of Avis customers who were charged a \$0.75 surcharge for earning frequent-flyer miles and other rewards through their participation in Avis's Travel Partner Program (the "Program").

The Program allows participating customers who rent a car from Avis to earn frequent-flyer miles or other rewards with certain airlines, hotels, and other companies (Avis's "Travel Partners"). Avis pays its Travel Partners for the points and miles earned by customers who participate in the Program, and also pays federal taxes on these points and miles. To offset part of its costs, Avis charges participating customers \$0.75 per rental day.

On May 15, 2011, Plaintiff made an online reservation on Avis's website for a rental vehicle between May 15-16, 2011. Plaintiff was to pick up, and return his vehicle at Manchester-Boston Regional Airport. According to Plaintiff, Avis's website prompted him to enter his Continental Airlines frequent-flyer number so that he could earn miles through the Program. Upon completing his online reservation, Plaintiff received an email confirmation containing an itemized list of estimated rental costs, which did not include any charge for earning frequent-flyer miles or rewards through the Program. The email read:

Tax (9.0%)

\$9.92

Rental Options

GPS Navigation

\$13.95

Additional Fees

Optional equipment and coverages may be subject to taxes and fees that are not included in the estimated total

Where2 GPS Navigation—Taxes not included.

Gas Service Option—Fees for the Gas Service Option are not included in the Estimated Total.

As a participant in Avis's Preferred Service Program, Plaintiff was able to bypass the service counter and proceed directly to his rental vehicle on the date of his arrival at Manchester–Boston Regional Airport. Plaintiff claims that Avis placed a document confirming the terms of the rental (the “Rental Document”) inside his rental car. The Rental Document included a list of the same itemized charges that had appeared in the email confirmation that Plaintiff received, as well as a \$0.75 daily surcharge described as an “FTP SUR” charge. When Plaintiff returned the car, Avis issued him a receipt (the “Return Document”) that again listed all the charges for the rental, and a \$0.75 charge described as “FTP–SR.”

*2 On July 16, 2014, Plaintiff moved to certify his claims for: (1) violation of the New Jersey Consumer Fraud Act (“NJCFRA”), N.J.S.A. § 56:8–1 et seq.; (2) breach of contract; and (3) breach of the covenant of good faith and fair dealing. [CM/ECF No. 146.] On the same day, Defendants moved to exclude the testimony of Plaintiff's expert. [CM/ECF No. 149.]

II. LEGAL STANDARD**A. Motion to exclude**

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. Rule 702 allows a witness qualified as an expert to give testimony if the expert's scientific, technical or specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue if: (i) the testimony is based upon sufficient facts or data, (ii) the testimony is the product of

reliable principles and methods, and (iii) the expert witness has applied the principles and methods reliably to the facts of the case. Fed.R.Evid. 702. The Third Circuit has explained that Rule 702 “embodies a trilogy of restrictions on expert testimony: qualification, reliability, and fit.” *Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir.2003) (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741–43 (3d Cir.1994)).

The District Court is required to act as a gatekeeper, preventing the admission of opinion testimony that does not meet these three requirements. *Id.* (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993)). The proponent of the evidence bears the burden of establishing the existence of each factor by a preponderance of the evidence. *Daubert*, 509 U.S. at 592; *In re Paoli*, 35 F.3d at 743–44. A court's rejection of expert testimony should be the exception rather than the rule. Fed.R.Evid. 702 Advisory Committee Note. As the Supreme Court noted in *Daubert*, “vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” 509 U.S. at 595.

B. Motion to certify

Class certification is proper only “if the trial court is satisfied, after a rigorous analysis, that the prerequisites of Rule 23 are met.” *In re Hydrogen Peroxide Antitrust Litigation*, 552 F.3d 305, 309 (3d Cir.2008) (quoting *Gen. Tel. Co. of Sw. v. Falcon*, 457 U.S. 147, 161, 102 S.Ct. 2364, 72 L.Ed.2d 740 (1982)). To meet the prerequisites of Rule 23, a plaintiff must establish both that the four requirements of Rule 23(a) have been met—numerosity, commonality, typicality, and adequacy—and that the pleading requirements of Rule 23(b)(1), (2), or (3) have been met. Fed.R.Civ.P. 23; see also *Hydrogen Peroxide*, 552 F.3d at 309 n. 6. The plaintiff bears this burden by a preponderance of the evidence. *Hydrogen Peroxide*, 552 F.3d at 320. Rule 23(b)(3) requires that a plaintiff also establish “that the questions of law or fact common

to the class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.” *Fed.R.Civ.P.* 23(b)(3); *see also Hydrogen Peroxide*, 552 F.3d at 310.

*3 When determining whether these requirements have been met, “the district court must make whatever factual and legal inquiries are necessary and must consider all relevant evidence and arguments presented by the parties.” *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 591 (3d Cir.2012) (quoting *Hydrogen Peroxide*, 552 F.3d at 307). “This is true even if the class certification inquiry overlaps with the merits of the causes of action.” *Id.*

III. ANALYSIS

A. Motion to Exclude

Before this Court can consider whether class certification is appropriate in this case, it must decide whether it should exclude the testimony of Plaintiff's expert witness. As discussed below, Defendants argue that Plaintiff does not meet the predominance requirement for *Rule 23* certification of the NJCFA claim because he cannot show that: (i) the disclosures of the frequent-flyer miles surcharge was not knowable to a significant number of class members, or (ii) if the surcharge had been knowable, most class members would not have signed up for Avis's frequent-flyer program. (Def.Br.15–16, 19–20) (relying on *Marcus*, 687 F.3d at 607–08). In arguing that the present case satisfies either of the two *Marcus* prongs, Plaintiff relies on the expert report of Dr. Vicki Morwitz. Defendants have moved to exclude this report, arguing that it does not comply with the standards of admissibility set forth by the United States Supreme Court in *Daubert*. Because the exclusion of Dr. Morwitz's report would defeat Plaintiff's attempt to certify his NJCFA claim, this Court will address Defendants' Motion to Exclude before addressing the merits of Plaintiff's Motion to Certify.

In order for a witness to be deemed qualified to testify as an expert, he or she must possess specialized knowledge, skill, experience, training or education. *Fed.R.Evid.* 702; *Schneider*, 320 F.3d at 407; *In re Paoli*, 35 F.3d at 741. Furthermore, testimony is said to be reliable if it is “based on the methods and procedures of science rather than on subjective belief or unsupported speculation.” *In re Paoli*, 35 F.3d at 741–43. In other words, the expert must have a reliable basis for his or her belief. *Id.*; *see also Daubert*,

509 U.S. at 590 (stating that proposed testimony must be supported by appropriate validation). Lastly, in order for expert testimony to be deemed fit, it must be relevant for the purposes of the case and must assist the trier of fact. *Schneider*, 320 F.3d at 404.

Defendants do not argue that Dr. Morwitz is not qualified to speak on the underlying subject or that her opinions are not relevant to the issues in this case. Instead, Defendants solely argue that Dr. Morwitz's opinions as to the two *Marcus* prongs are unreliable. The Court will address these arguments in turn.

1. The Knowability Prong of *Marcus*

In her report, Dr. Morwitz concludes that during the relevant time periods, “virtually none” of Defendants' customers could have known that they were being charged a surcharge for earning frequent-flyer miles. (Docket # 146–15.) To support this opinion, Morwitz relies on (i) a number of documents that contain the surcharge disclosure, (ii) data regarding the number of visitors to Avis's website, (iii) data from other airlines concerning how they distribute frequent-flyer miles, and (iv) scholarly literature.

*4 Defendants first argue that Dr. Morwitz's report is unreliable because she did not conduct a survey of Avis's customers to determine whether they were aware of the surcharge. (Def.Br.18.) However, Defendants have not cited to a case that holds that the lack of a consumer survey automatically renders an expert's report inadmissible. At the same time, their reliance on *Neale v. Volvo Cars of N. Am., LLC*, No. 10–4407, 2013 WL 784962 (D.N.J. Mar.1, 2013) is misplaced. In *Neale*, the defendants' expert issued an opinion regarding the ineffectiveness of a recall notice, citing to a study “demonstrating that on average 70% of vehicle owners responded to recall notices, with response rates as low as 23% and as high as 96%.” *Id.* at *3. The court found the expert's opinion to be unreliable because the expert did not determine where Volvo owners fall within that range, and if such owners “have an average response rate on the higher end of that range, [the expert] could not argue that a reasonable person would not respond to a recall notice about the alleged defect.” *Id.* This problem does not exist in the present case, as Dr. Moritz does not rely on a study that yields results of such a wide range. Though she uses academic literature to inform her opinion, Plaintiff's expert relies on the available web traffic data of Avis.com to determine that almost no

customers clicked on the different links that contained information about the frequent-flyer miles surcharge. This data showed that, from January 2009 to June 2012, less than 1% of the customers that visited Defendants' website clicked on the surcharge information links.

Defendants also take issue with Dr. Morwitz's analysis of the Rental Documents. For example, Defendants point to Dr. Morwitz's reliance on a study that concludes that 85% of customers do not examine supermarket receipts for accuracy, and argue that because this study shows that 15% of supermarket customers *do* examine their receipts, her opinion is unreliable. This Court, however, fails to see how a study confirming that only a minority of customers examine their receipts undermines Dr. Morwitz's conclusion.² Defendants also argue that Dr. Morwitz's opinion that most consumers would not understand that "FTP SUR" is shorthand for "Frequent Traveler Surcharge Program" is unreliable because the only way to know what consumers understood would be to look at empirical data or ask each consumer directly. However, in concluding that this shorthand is an example of price obfuscation, "which means presenting price information in a manner that is confusing to consumers and designed not to be noticed or processed carefully," (Morwitz Report at 23), Dr. Morwitz relies on literature concerning this practice. (*See id.* at 12.) Thus, Defendants are incorrect in arguing that Morwitz's opinion is based only on her subjective beliefs. If anything, the absence of a study conducted by Plaintiffs' expert regarding consumers' reactions to the "FTP SUR" shorthand is relevant to the weight, not the admissibility, of her conclusion. *See In re TMI Litig.*, 193 F.3d 613, 692 (3d Cir.1999) *amended*, 199 F.3d 158 (3d Cir.2000) ("So long as the expert's testimony rests upon 'good grounds', it should be tested by the adversary process ... rather than excluded from juror's scrutiny for fear that they will not ... satisfactory weigh its inadequacies."). Finally, Defendants criticize Dr. Morwitz's conclusion that the Rental Documents are insufficient because they are received after the rental has already concluded, arguing that most customers are repeat renters and therefore had numerous opportunities to learn of the surcharge. However, because Dr. Morwitz concludes that most consumers do not examine their receipts for accuracy, the fact that most customers are repeat renters is not dispositive.

*5 Defendants' third set of arguments focuses on Dr. Morwitz's critique of the surcharge disclosures on Avis's website. In concluding that Avis's website did not inform consumers of the surcharge during the relevant time periods, she relies on data that shows that from January 2009 through June 2012, a very insignificant number of visitors to Avis.com viewed the webpage that provided information about the surcharge. For example, in January 2009, of the 2,272,074 visitors to Avis.com, only .007% clicked through to this page. Defendants argue that this data is unreliable because some consumers may have visited the disclosure webpage before 2009, and some may have already been aware of the surcharge and therefore had no reason to visit the disclosure webpage. However, these arguments rest on speculation, and Dr. Morwitz's reliance on data that does not extend earlier than January 2009 is only relevant to the weight of her testimony, not its admissibility. *See In re Front Loading Washing Mach.*, No. 08-51, 2013 WL 3466821, at *8 (D.N.J. July 10, 2013) (finding that while an expert's testimony would have been stronger if he conducted a test in a more accurate manner, "this factor goes to weight and not admissibility"). Defendants also argue that Dr. Morwitz's opinion that a reasonable consumer would have been confused by Avis's labeling of the surcharge as a "tax" on its website is unreliable because Morwitz points to no evidence to support this proposition. However, in forming her opinion, she relies on academic literature concerning the way consumers react to the word "tax" (*see* Morwitz Report at 19), and as discussed above, the fact that Dr. Morwitz did not gather her own data does not render her opinion inadmissible.

Finally, Defendants argue that Dr. Morwitz's opinion ignores additional ways in which the surcharge was disclosed, including (i) advertisements that Avis placed in various periodicals, and (ii) disclosures that appeared on the webpages of airlines. However, to the extent that Defendants wish to use their own evidence to contradict Dr. Morwitz's report, the appropriate time to do so is not in a motion to exclude. Instead, Defendants' evidence and arguments will be considered during this Court's class certification analysis.

Accordingly, this Court does not find that Dr. Morwitz's report regarding the knowability prong of *Marcus* is unreliable under *Daubert*.

2. The Materiality Prong of *Marcus*

In her report, Morwitz concludes that “even had Avis's frequent-flyer surcharge been knowable to consumers, only an insignificant number of them would likely have purchased these miles and have paid Avis's surcharge anyway.” (Morwitz Report at 26.) To support this opinion, Morwitz relies on (i) academic literature that demonstrates that consumers enjoy receiving products that are offered for free, (ii) her independent analysis that verifies that the vast majority of frequent-flyer miles that consumers can obtain are available without a surcharge or fee, and (iii) academic literature that suggests that consumers are less likely to buy products when these products cost more than what consumers expect them to cost.

*6 Defendants first argue that Morwitz's opinion regarding materiality is unreliable because Morwitz did not conduct a survey or gather any empirical data concerning the amount that Avis customers might expect frequent flyer miles to cost, and instead bases her conclusions on her own subjective beliefs. However, while Morwitz did not gather any data, she relies on scholarly literature and data from other airline. Thus, her opinion is not, as Defendants suggest, completely unfounded. Further, the two cases cited by Defendants to support this argument are distinguishable from the present case. In *Bowers v. Nat'l Collegiate Athletic Ass'n*, 564 F.Supp.2d 322, 356 (D.N.J.2008), the Court excluded expert testimony regarding “accommodations and support that are available to learning disabled college students, and the success of such students in college.” The Court found the expert's testimony to be unreliable because he relied solely on his own experience and did not explain why that experience was a sufficient basis for his opinion. *Id.* at 357. Further, when plaintiff's counsel emailed the expert explaining the testimony that she needed, the expert replied that he would “ask around on the student athletes with disabilities,” which the court found to be suspect. *Id.* Such issues are not present in this case. Defendants also cite to *American Home Products Corp. v. Procter & Gamble Co.*, 871 F.Supp. 739 (D.N.J.1994) for the proposition that a survey is needed to support an expert's opinion regarding consumer expectations. However, *American Home Products* was a Lanham Act case wherein the Court stated that “[b]ecause [p]ublic reaction is the measure of a commercial's impact, an implied falsity claim [under the Lanham Act] must be proven in a false advertising case via the use of a consumer

survey.” As such, *American Home Products* is inapplicable to the present case.

Second, Defendants complain that Morwitz's opinion that most consumers are able to receive frequent-flyer miles for free is “entirely unsupported (and in fact, is incorrect).” (Defs' Mot. at 19). However, Morwitz's opinion is not “entirely unsupported,” as she bases her conclusion on data from multiple airlines concerning the way they distribute their frequent-flyer miles. (See Morwitz Report at 28.) Whether or not her conclusion is incorrect is a question that should not be answered when the Court is determining whether to exclude an expert under *Daubert*. See *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145–46 (3d Cir.2000) (“The test of admissibility is not whether a particular scientific opinion has the best foundation or whether it is demonstrably correct. Rather, the test is whether the particular opinion is based on valid reasoning and reliable methodology.” (internal quotations and citation omitted))

Finally, Defendants argue that Morwitz's opinion is undermined by a survey conducted by Defendants' expert, Dr. Ravi Dhar, whereby Dhar shows that roughly the same number of respondents opt for frequent flyer miles whether the surcharge is disclosed (96.7% of respondents) or not (97.5% of respondents). However, while Defendants may attempt to impeach Morwitz using this survey, it does not serve as a basis for excluding her report. See *Daubert*, 509 U.S. at 595 (stating that the “presentation of contrary evidence ... [is a] traditional and appropriate means of attacking shaky but admissible evidence”); *In re Jacoby Airplane Crash Litig.*, No. CIV. 99–6073, 2007 WL 2746833 (D.N.J. Sept. 19, 2007) (“As Plaintiffs persuasively argue ... [d]isagreement of another expert does not render a report untrustworthy.” (internal quotations omitted)).

*7 Accordingly, Defendants' Motion to Exclude is denied.

B. Motion to Certify

1. Class Definition

Before considering whether Plaintiff has met the requirements for Rule 23 certification, this Court must first determine whether the proposed “parameters defining the class or classes to be certified” are “readily discernible, clear, and precise[.]” *Marcus*, 687 F.3d at 591

(quoting *Wachtel v. Guardian Life Ins. Co.*, 453 F.3d 179, 187 (3d Cir.2006)). Plaintiffs define the proposed class as:

All Avis Preferred members with a United States address who, until June 14, 2012, rented a vehicle through www.avis.com and who paid a surcharge for receiving frequent-flyer miles from any of Defendants' travel partners.

(Pl.Br.2.) Defendants do not challenge the parameters of Plaintiff's class definition.

Here, the proposed class members enrolled in Avis's Preferred program, rented a vehicle through Defendants' website, and purchased frequent-flyer miles. As such, Defendants have a record of their contact information and the amount of money they spent on the frequent-flyer mile surcharges. This is sufficient for this Court to conclude that the proposed class definition is "readily discernible, clear, and precise." *Marcus*, 687 F.3d at 591.

2. Class Certification

Plaintiff seeks class certification under Federal Rule of Civil Procedure 23(b)(3) for his claims for: (1) violation of the NJCFA; (2) breach of contract under New Jersey common law; and, (3) violation of Defendants' duty of good faith and fair dealing. Rule 23(b)(3) provides that in order to maintain a class action, the Court must first determine that the prerequisites of Federal Rule of Civil Procedure 23(a) are satisfied, in addition to the requirements of 23(b)(3). Rule 23(a) requires a showing of (1) numerosity; (2) commonality; (3) typicality; and (4) adequacy of representation. *Georgine v. Amchem Prods.*, 83 F.3d 610, 624 (3d Cir.1996) (citing Fed.R.Civ.P. 23(a)). In addition, Rule 23(b)(3) requires a finding "that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy." Fed.R.Civ.P. 23(b)(3).

Defendants argue that Plaintiff's motion should be denied because: (1) Plaintiff's claims are not typical of those of the class he purports to represent; (2) a class action is not the superior method for adjudication of this case; (3) Plaintiff and his counsel "may not" satisfy the adequacy requirement under Rule 23; and (4) individual issues

predominate over common ones. Though they do not challenge the numerosity and commonality requirements for certification, this Court will consider all of the Rule 23 requirements in turn.

1. Numerosity

Rule 23(a)(1) provides that the proposed class must consist of members that are so "numerous that joinder of all members is impracticable." Fed.R.Civ.P. 23(a)(1). "Impracticability does not mean impossibility but only the difficulty or inconvenience of joining all members of the class." *Zinberg v. Washington Bancorp, Inc.*, 138 F.R.D. 397, 406 (D.N.J.1990) (quoting *Harris v. Palm Springs Alpine Estates, Inc.*, 329 F.2d 909, 913-14 (9th Cir.1964)). Similarly, this Court has held that "[t]o meet the numerosity requirement, class representatives must demonstrate only that 'common sense' suggests that it would be difficult or inconvenient to join all class members." *Varacallo v. Massachusetts Mut. Life Ins. Co.*, 226 F.R.D. 207, 229 (D.N.J.2005) (quoting *In re Prudential Ins. Co. of Am. Sales Practices Litig.*, 962 F.Supp. 450, 507 (D.N.J.1997) *aff'd sub nom. In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283 (3d Cir.1998) (hereinafter "*Prudential I*"). Joinder of a class that numbers in the hundreds will normally be found impracticable, although the numerosity requirement is usually satisfied with much smaller classes. See *Prudential I*, 962 F.Supp. at 510 (citing 1 Herbert Newberg & Alba Conte, *Newberg on Class Actions* § 3.05, at 3-25).

*8 Here, Plaintiff argues that joinder of all Class Members is impracticable because "11.9 million rental transactions" that "involved a frequent-flyer surcharge" occurred through Defendants' website between January 2005 and August 2011. (Pl.Br.7-8) (citing Docket # 146-16.) This amount of rental transactions is sufficiently high to make joinder of all the class members difficult or impractical. See *Prudential I*, 962 F.Supp. at 510. Defendants have not presented evidence showing otherwise. Thus, this Court finds that the numerosity requirement of Fed.R.Civ.P. 23(a)(1) is satisfied.

2. Commonality and Predominance

It is customary in Rule 23(b)(3) class actions for courts to jointly apply the Rule 23(a)(2) commonality requirement and the Rule 23(b)(3) predominance test. See *Varacallo*, 226 F.R.D. at 230. The Third Circuit has approved

this approach. See *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 528 (3d Cir.2004) (“[T]he Rule 23(b)(3) predominance requirement, which is far more demanding, incorporates the Rule 23(a) commonality requirement.... Accordingly, we analyze the two factors together” (citations omitted)); *Amchem Prods.*, 83 F.3d at 626.

Under Rule 23(a)(2), commonality is satisfied if “there are questions of law or fact common to the class.” Fed.R.Civ.P. 23(a)(2). Not all claims or facts have to be common to all class members; “the commonality requirement will be satisfied if the named plaintiffs share at least one question of fact or law with the grievances of the prospective class.” *Prudential I*, 148 F.3d at 310; *Baby Neal v. Casey*, 43 F.3d 48, 56 (3d Cir.1994).

However, for a class that is certified under Rule 23(b)(3), which the Plaintiffs are here seeking, the Court must also find that these common questions predominate over individual issues. *Prudential I*, 962 F.Supp. at 510–11. “To assess predominance, a court at the certification stage must examine each element of a legal claim ‘through the prism’ of Rule 23(b)(3).” *Marcus*, 687 at 600 (quoting *In re DVI, Inc. Sec. Litig.*, 639 F.3d 623, 630 (3d Cir.2011)). A plaintiff must “demonstrate that the element of [the legal claim] is capable of proof at trial through evidence that is common to the class rather than individual to its members.” *Id.* (quoting *Hydrogen Peroxide*, 552 F.3d at 311). “In cases where it is alleged that the defendant ... engaged in a common course of conduct, courts have found that conduct to satisfy the commonality and predominance requirements.” *Varacallo*, 226 F.R.D. at 231. In addition, the need to calculate “damages on an individual basis should not preclude class [certification] when the common issues which determine liability predominate.” *Holmes v. Pension Plan of Bethlehem Steel Corp.*, 213 F.3d 124, 137 (3d Cir.2000); see also *Bogosian v. Gulf Oil Corp.*, 561 F.2d 434, 456 (3d Cir.1977).

Defendants do not contest that the commonality requirement is satisfied. Instead, they argue that Plaintiff does not satisfy the predominance requirement of Federal Rule of Civil Procedure 23(b)(3) for neither the NJCFA claim nor the common law breach of contract and breach of duty of good faith and fair dealing claims. (Def.Br.22.)

i. Predominance of Plaintiff's NJCFA claim

*9 To establish a cause of action under the NJCFA, a plaintiff must show: (a) an unlawful conduct by the defendant; (b) that the plaintiff suffered an ascertainable loss; and, (c) a causal connection between defendant's unlawful conduct and plaintiff's ascertainable loss. *Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merk & Co., Inc.*, 192 N.J. 372, 929 A.2d 1076, 1086 (N.J.2007) (quoting N.J.S.A. § 56:8–2).

Here, Plaintiff argues that Defendants engaged in two different types of unlawful conduct: intentional omissions and unconscionable commercial practices. (Compl. at ¶¶ 61–62; Pl. Br. 15–16.) According to Plaintiff, Defendants knowingly omitted the fact that Avis charged \$0.75 a day for participating in its Program “by both failing to include [this fact] in a place where Plaintiff and other reasonable renters would expect to see them and by instead (to the extent that any disclosure was made at all) hiding these facts in obscure places with the intention that neither Plaintiff nor other reasonable renters ever see them[.]” (Compl. at ¶ 61.) The unconscionable commercial practices alleged by Plaintiff are premised on this omission. (Docket # 57, fn 3.)

Plaintiff argues that the class will be able to prove the unlawful conduct element with common evidence because Defendants' actions were uniform as to all members of the class. (Pl.Br.15–16.) This Court is satisfied that Plaintiff will be able to prove this element using common evidence given the fact that Avis entered into a standard form contract with millions of customers over the class period and that the surcharge information was presented in similar manner to most Avis customers for that period.

Regarding the ascertainable loss element, Plaintiff argues that “class members need merely show the amount of the surcharge they paid to Defendants, which is easily discernable from Defendants' transaction data.” (Pl.Br.18.) This Court agrees. An ascertainable loss is “either out-of-pocket loss or a demonstration of loss in value ... that it is quantifiable or measurable.” *Thiedemann v. Mercedes-Benz USA, LLC*, 183 N.J. 234, 872 A.2d 783, 792 (N.J.2005). Here, the ascertainable loss is the amount paid in surcharges for participation in the Program, which is easily quantifiable and measurable.

Finally, Plaintiff argues that the class can prove the causality element of the NJCFA claim with common evidence. The determination of whether common

questions predominate over individual ones regarding this final element depends on the type of unlawful conduct alleged by the plaintiff. When the alleged unlawful conduct is a “knowing omission,” a court must find:

[E]ither (1) that the alleged [omissions] were not knowable to a significant number of potential class members before they purchased ... [the product], or (2) that, even if the [omissions] were knowable, that class members were nonetheless relatively uniform in their decision-making, which would indicate that, at most, only an insignificant number of class members actually knew of the alleged [omissions] and purchased ... [the product] at the price they did anyway. These finding cannot be side-stepped. They are necessary to determine whether the predominance requirement is met in this case.

***10** *Marcus*, 687 F.3d at 610.³

With respect to the first *Marcus* prong, Defendants argue that Plaintiff fails to meet the predominance requirement because the information regarding the \$0.75 surcharge was knowable. (Def.Br.15.) They attempt to demonstrate this by presenting several ways in which the surcharge was disclosed and arguing that a significant number of customers knew about the surcharge given the aggregate sources of information. This is unpersuasive, especially considering that all of the rentals in question were done exclusively through Avis's website. At the same time, Defendants do not present expert opinion to establish that the surcharge was knowable. Instead, Defendants' expert only addresses the “knowability” prong by questioning the reliability of Plaintiff's expert's testimony. Given the evidence presented by the parties, including their experts' testimonies, this Court concludes that the information about the surcharge was “not knowable to a significant number of potential class members [.]” *Marcus*, 687 F.3d at 610.

Avis did not suitably disclose the surcharge on their webpage from 2005 to June 2012, when the class period ends. Though Defendants claim that “Preferred Customers were always able to see that a \$0.75–

per–rental–day surcharge would be assessed if they opted to obtain frequent flyer miles[.]” because they provided different links to this information throughout the car rental process, the links they describe were not conspicuously presented to customers. (Def. Br. 7–8, fn 6.) From 2005 to January 2009, the surcharge was disclosed through a web link “that appeared on the bottom of the web page on which members of Avis's Preferred Service Program ... would enter their profile information, information regarding their membership in any relevant frequent travel programs, and their travel preferences.” (Docket # 146–9, 4.) According to Plaintiff's expert, Dr. Morwitz, it would have been unlikely for a customer to have noticed this link at the bottom of that page. (Docket # 146–15, 12.) In support, she points to the January 2009 data of webpage visits for Avis.com, which shows that out of 2,272,074 unique visitors to the site, only 165 people clicked on the link that provided the surcharge information. (*Id.* at 13.) The expert states that this sample, although small, is indicative of the web traffic since 2005. (*Id.*) She based this opinion on “both the data on webpage viewership for the end of this time period, data for the later time period, and the consistency of these data across time, as well as on academic literature[.]” (*Id.* at 13–14.)

Dr. Morwitz also points out that the link was presented “far from webpages where Avis list[ed] other rental-car-cost information[.]” (*Id.* at 13.) Because of this, she describes the surcharge information as a “shrouded attribute,” or “information that firms hide or obfuscate from their customers.” (*Id.* at 12.) She supports this statement with studies about how consumers have incomplete pricing information when companies “make finding price information complicated, difficult, or confusing.” (*Id.*)

***11** From January 2009 to May 2012, Avis moved the link that disclosed the surcharge to “a webpage originating under the major heading ‘Cars and Services.’” (*Id.* at 17.) In order to locate the link, a customer would have had to click on “Cars and Services,” then “Miles & Points/Partners,” then “Airlines,” and then choose an airline. (*Id.*) Once the airline was chosen, a link entitled “Click here for Frequent Traveler Tax/Surcharge Information” was located near the bottom of the page. (Docket # 146–9, 5.) Dr. Morwitz considers this another example of “shrouded attribute.” She explains that in order to find the link during this period, a customer would have had to start the search for this information under the tab labeled “Cars

and Services,” a title which is “reasonably unrelated to Avis’s surcharge.” (Docket # 146–15, 17–18.) She explains that during this period “virtually no consumers viewed Avis’s frequent-flyer surcharge information.” (*Id.* at 18.) She also argues that even if a customer reached the page with the surcharge disclosure link, the title of that link, “Frequent Traveler Tax,” is confusing and would not lead people to think that it discloses a surcharge for frequent flyer miles. (*Id.*) She supports this argument with academic literature that explains how people interpret a cost labeled as a “tax” rather than a “surcharge.” (*Id.* at 19–20.)

Finally, for the period between May 2012 and June 2012, Defendants moved the link disclosing the surcharge to the page for “step 4 of the online reservation process.” (Docket # 146–9, 7.) The link was titled “Help?” and was located in the section of the page where customers could enter their flight information. (*Id.*) If customers clicked on the “Help?” link, they would be sent to a different page with a link titled “Frequent-Flyer Tax Recovery/Surcharge.” (*Id.*) Dr. Morwitz again explains that virtually no customers clicked on this link during this period. (Docket # 146–15, 21.) Her analysis for this period is similar to the analysis of the periods explained above.

Defendants’ expert, Dr. Dhar, criticizes this analysis because Dr. Morwitz does not use “empirical analysis” to reach her conclusions. (Docket # 147–5, 3.) However, Dr. Dhar does not present his own empirical data as a counterargument. Instead, he points to different sources from which a customer might have gotten notice of the surcharge. He concludes, without support, that “it is likely that individual renters would have differed as to their awareness of the surcharge depending upon their attention to these sources.” (*Id.* at 8.) Dr. Dhar also points out that Dr. Morwitz did not consider the changes made to the surcharge disclosure in February 2013. (*Id.* at 7.) He argues that “[t]his is significant in light of the large number of members of the putative class who visited the Avis website after February 2013 and likely had knowledge of the surcharges based on the online rental reservation process on the website alone.” (*Id.*) This criticism, however, is irrelevant because the class period ends in 2012.

*12 Dr. Dhar also suggests that Dr. Morwitz’s conclusion is flawed because she does not take into account whether the customers that visited the Avis

website did not click on the surcharge disclosure links because they had previously discovered said surcharge. (*Id.* at 8.) However, Dr. Morwitz does consider this. As explained above, she considers how few people clicked on the link for a period of time, and took into account the consistency of the data throughout that time. She also relies on studies that show that “the more often a consumer visits the same website, the less time this consumer spends on that website.” (Docket # 146–15, 12.) Based on this, Dr. Morwitz concluded that repeat renters were less likely to deviate from the pages that they needed to visit in order to make a car rental. (*Id.* at 15–16.)

Given Dr. Morwitz’s expert analysis, this Court concludes that the surcharge information was not knowable. Though Defendants argue otherwise by pointing to sources other than the Avis website through which customers could have discovered the surcharge, this Court finds this unpersuasive. The rental documents did not disclose the surcharge to Plaintiff before he finalized the car rental online because they were given to him when he picked up his car and once he returned it. Moreover, the surcharge was listed in these documents under the code “FTP SUR” and “FTP-SR.” Similarly, the e-Receipt was sent to Plaintiff after the car was returned.

Additionally, Defendants point to print ads as a source of disclosure. However, these ads mention the surcharge in the fine print. Moreover, Defendants do not present any evidence regarding where these ads were published or the rate of circulation. They also argue that members of the putative class could have discovered the surcharge by visiting their Travel partners’ webpages. Yet, Defendants acknowledge that these pages stated that a surcharge “may” apply, not “will apply.”

Finally, Defendants argue that Plaintiff should have known about the surcharge because charging for frequent-flyer miles is common knowledge. Plaintiff’s expert concludes that “consumers do not need to pay a fee to obtain frequent-flyer miles from the airlines themselves.” (Docket # 146–15, 29.) Dr. Morwitz based this opinion on different airlines’ data of the total of frequent flyer miles that were earned and redeemed by their customers “(1) from their own flights; (2) from flights on their partner airlines; and (3) through rental-car companies, hotels, credit cards, miles sold to customers, and other means.” (*Id.*) With this information, she concluded that for the period between 2005 and 2012,

over 91% of the frequent-flyer miles made available by airlines were earned “for no additional cost.” (*Id.* at 31.) Defendants’ expert, Dr. Dhar, attempts to rebut this claim by pointing out that most credit card companies that offer miles charge a fee and that other car rental companies charge similar surcharges. (Docket # 147–5, 4.) However, Defendants’ evidence, in light of Dr. Morwitz’s expert testimony, does not show that “charging for frequent-flyer miles is common knowledge.”

*13 Because this Court finds that the surcharge was not knowable, it is unnecessary to consider the second prong of the *Marcus* test.

ii. Predominance of the common law claims

To state a claim for breach of contract, a plaintiff must allege (1) a contract between the parties; (2) a breach of that contract; (3) damages flowing therefrom; and (4) that the party stating the claim performed its own contractual obligations. *Frederico v. Home Depot*, 507 F.3d 188, 203 (3d Cir.2007). Moreover, “[t]he party claiming a breach of the covenant of good faith and fair dealing ‘must provide evidence sufficient to support a conclusion that the party alleged to have acted in bad faith has engaged in some conduct that denied the benefit of the bargain originally intended by the parties.’” *Brunswick Hills Racquet Club, Inc. v. Route 18 Shopping Ctr. Assocs.*, 182 N.J. 210, 864 A.2d 387, 396 (N.J.2005) (relying on 23 Williston on Contracts §§ 63:22 (Lord ed.2002); *Wilson v. Amerada Hess Corp.*, 168 N.J. 236, 773 A.2d 1121 (N.J.2001); and *Sons of Thunder, Inc. v. Borden, Inc.*, 148 N.J. 396, 690 A.2d 575 (N.J.1997)). “[B]ad faith normally connotes an ulterior motive or sinister purpose.” *McPherson v. Employees’ Pension Plan of Am. Re-Insurance Co.*, 33 F.3d 253, 256–257 (3d Cir.1994). “A plaintiff may be entitled to relief under the covenant if its reasonable expectations are destroyed when a defendant acts with ill motives and without any legitimate purpose.” *Brunswick Hills Racquet Club*, 864 A.2d at 396 (quoting *Wilson*, 773 A.2d at 1130).

Plaintiff argues that these common law contract claims can be proven with common evidence because they arise out of a uniform contract. (Pl.Br.11.) (“[W]here the contract at issue is uniform to all class members, courts often find that common issues predominate.”). Here, the terms of the contract between Plaintiff and Defendants are substantially similar to those entered between the putative class members and Defendants. (See Docket # 146–12; 146–13; 146–14; 146–15.) Moreover, Defendants’

behavior is uniform for all members of the putative class. Whether Defendants charged a hidden surcharge for frequent-flyer miles is a question that will be answered equally for all members of the class. Similarly, whether the class members performed their own contractual obligations can be answered with common evidence by looking at Defendants’ rental records. Because Plaintiff’s claim for breach of the covenant of good faith and fair dealing arises out of his breach of contract claim, the putative class will be able to prove this claim with the same common evidence.

Defendants argue that Plaintiff fails to establish the predominance requirement for these claims because each member of the class “would have to show that he/she has the injury-in-fact that would prove the causation and damages required for the contract-related claims alleged here.” (Def.Br.22.) This Court disagrees. Defendants seem to recast the jurisdictional challenge they asserted in their motion for summary judgment as a reason to deny class certification. This Court has already dismissed this argument. See *Schwartz v. Avis Rent a Car Sys., LLC*, No. 11–4052, 2014 WL 3866476 (D.N.J. Aug.6, 2014).

3. Superiority

*14 In addition to predominance, Rule 23(b)(3) requires that “a class action [be] superior to other available methods for the fair and efficient adjudication of the controversy.” Fed.R.Civ.P. 23(b)(3). In making its superiority determination, the Court will consider four nonexclusive factors:

- (1) the interest of individual members of the class in individually controlling the prosecution of the action;
- (2) the extent of litigation commenced elsewhere by class members;
- (3) the desirability of concentrating claims in a given forum;
- and (4) the management difficulties likely to be encountered in pursuing the class action.

See Fed.R.Civ.P. 23(b)(3); *Prudential I*, 962 F.Supp. at 522. Considering these factors, this Court concludes that a class action is the superior form of adjudication.

Regarding the first factor, Plaintiff argues that “a class action is the only economically feasible way for a class

members to recover their damages from Defendants[]” because the individual damages are “small multiples of \$0.75.” (PL Br. 26.) This Court agrees. The cost of prosecuting these claims individually will outweigh the financial benefit any one plaintiff would gain if successful at trial. As such, “the interest of most class members in conducting separate lawsuits” is not sufficiently “strong as to require denial of class certification.” *Prudential I*, 962 F.Supp. at 523.

The second and third factors, though not addressed by either party, do not weigh against class certification. As far as this Court is aware, there is no litigation commenced elsewhere by class members. Moreover, there is no evidence showing that a different forum has a greater interest in this action. Instead, New Jersey has a strong interest in resolving suits arising under New Jersey laws.

With respect to the fourth factor, management difficulties “encompass[] the whole range of practical problems that may render the class action format inappropriate for a particular suit.” *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 164, 94 S.Ct. 2140, 40 L.Ed.2d 732 (1974). “The Court must query not whether there will be any manageability problems, but whether reasonably foreseeable difficulties render some other method of adjudication superior to class certification.” *Prudential I*, 962 F.Supp. at 524–25; *Newberg on Class Actions* § 4:72 (“[T]he question that courts consider when they analyze manageability is not whether a class action is manageable in the abstract but how the problems that might occur in managing a class suit compare to the problems that would occur in managing litigation without a class suit.”). Since challenges to the manageability prong of the superiority requirement often arise when a case involves many individual issues, “the manageability concern often simply echoes the predominance analysis[.]” [t]herefore, courts generally hold that if the predominance requirement is met, then the manageability requirement is met as well.” *Newberg on Class Actions* § 4:72; *Prudential I*, 962 F.Supp. at 525 (finding that plaintiffs alleged “both the existence and predominance of common issues and demonstrate[d] the superiority of aggregate adjudication” because plaintiffs established that “they could offer classwide evidence with respect to both liability and damages[.]”).

*15 Defendants argue that adjudicating this suit as a class action will present management difficulties because

“the issues that would have to be decided here are individual, not common ones, and are not susceptible of class-wide proof.” (Def.Br.23) (internal quotations omitted). They contend that Plaintiff’s trial plan reflects these management difficulties. According to Defendants, the first-stage of the trial plan, which focuses on Defendants’ liability, improperly focuses “solely on Avis’s conduct, which directly conflicts with Third Circuit teaching.” (*Id.* at 24) (citing *Marcus*, 687 F.3d at 607). They further argue that the second and third stage improperly relies on an “ ‘aggregate’ or ‘class-wide’ damages model as a proxy for proving the ‘harm’ element of class members’ claims” in lieu of determining whether each class member has a valid claim. (*Id.* at 25.)

This is insufficient to show that managing this case as a class action is not the superior method of adjudication. As explained above, Defendants’ first argument is without merit because their reliance on *Marcus* is misplaced. The Third Circuit in *Marcus* did not reject the District Court’s conclusion that “a causal relationship between an alleged unlawful practice and a consumer’s ascertainable loss may be presumed ... when a defendant is alleged to have omitted material information ... and when a defendant’s marketing statements do not differ from one consumer to another[.]” *Marcus*, 687 F.3d at 607. Rather, the Circuit Court explained that the District Court failed to make the necessary findings of fact to justify this conclusion. *Id.* It reasoned that “before applying a ‘presumption of causation’ to an NJCFA claim, a court must consider not only the defendants’ course of conduct, but also that of the plaintiffs[.]” [s]pecifically ... whether plaintiffs could have known the truth underlying the defendant’s fraud.” *Id.* Unlike the district court in *Marcus*, this Court held that Defendants’ “knowing omission” was not knowable. As such, individual issues related to causation do not predominate over common ones.

Defendants’ interpretation of the second and third stages of the trial plan is also misplaced. Plaintiff is not attempting to prove harm by using an “aggregate” or “class-wide” damages model. Instead, he is proposing to calculate damages by using Defendants’ data on how many people paid the \$0.75 surcharge per day.

Moreover, both of Defendants’ arguments fail to consider the difficulties of trying this dispute without a class action. As mentioned above, it would be very difficult for each plaintiff to litigate his or her dispute with Avis individually

because the recoverable amount of damages are likely marginal. Accordingly, this Court finds that Plaintiff has satisfied the predominance requirement of Rule 23.

4. Typicality

Rule 23 also requires that “the claims or defenses of the representative parties are typical of the claims or defenses of the class.” Fed.R.Civ.P. 23(a)(3). This requirement “is said to limit the class claims to those fairly encompassed by the named plaintiff’s claims.” *General Tel. Co. v. EEOC*, 446 U.S. 318, 330, 100 S.Ct. 1698, 64 L.Ed.2d 319 (1980). “Typicality lies where there is a strong similarity of legal theories or where the claims of the class representatives and the class members arise from the same alleged course of conduct by the defendant.” *Prudential I*, 962 F.Supp. at 518 (citations omitted). In addition, “factual differences between the claims of the putative class members do not defeat certification.” *Prudential II*, 148 F.3d at 311 (quoting *Baby Neal*, 43 F.3d at 56).

*16 Here, Plaintiff has shown that the legal and factual issues that he asserts in his claims are very similar to those of the class. However, Defendants argue that “Plaintiff’s claims are not typical of those of the class he purports to represent” because Plaintiff did not suffer an injury-in-fact and, therefore, does not have Article III standing. (Def.Br.27–28.) Again, this Court has already held that Plaintiff did suffer an injury-in-fact when it denied Defendants’ motion for summary judgment. See *Schwartz*, No. 11–4052, 2014 WL 3866476. As such, Defendants’ argument is unpersuasive.

5. Adequacy of Representation

Rule 23(a)(4) requires that “the representative parties [must] fairly and adequately protect the interests of the class.” Fed.R.Civ.P. 23(a)(4). Courts look at two factors: “(1) the plaintiff’s attorney must be qualified, experienced, and generally able to conduct the proposed litigation, and (2) the plaintiff must not have interests antagonistic to those of the class.” *Prudential I*, 962 F.Supp. at 519. A party challenging the Class’ representation has the burden to prove that the representation is not adequate. *Id.*; *Varacallo*, 226 F.R.D. at 233.

Defendants neither question Plaintiff’s attorneys’ qualifications nor argue that Plaintiff’s interests are antagonistic to those of the class. Instead, they suggest that Plaintiff and his counsel “may not” satisfy the adequacy requirement because it is unclear how Plaintiff learned that he was charged for the frequent flyer miles. (Def.Br.29.) They imply that Plaintiff’s counsel told Plaintiff about his possible claim against Avis. (*Id.*) However, Defendants do not offer any evidence in support of this claim. As such, they fail to prove that the representation is not adequate.

IV. CONCLUSION

Based on the reasons set forth above, Defendants’ motion to exclude Plaintiff’s expert testimony [CM/ECF No. 149] is denied. Plaintiff’s motion to certify [CM/ECF No. 146.] is granted.

An appropriate Order accompanies this Opinion.

All Citations

Not Reported in F.Supp.3d, 2014 WL 4272018, 95 Fed. R. Evid. Serv. 350

Footnotes

- 1 Plaintiff’s Notice of Motion for Class Certification states that Plaintiff moves for certification under Federal Rules of Civil Procedure 23(b)(2) and 23(b)(3). [CM/ECF No. 146.] Rule 23(b) (2) states that “[a] class action may be maintained if Rule 23(a) is satisfied and if ... the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole[.]” Fed.R.Civ.P. 23(b)(2). As discussed with the parties during oral arguments on July 9th, 2014, Defendants ceased engaging in the practices complained about in this action at the end of the class period. Transcript of Oral Argument at 17, *Schwartz v. Avis*, 2014 WL 3866476 (No. 11–4052). As such, the issue of injunctive relief is no longer applicable to this case. Moreover, Plaintiff does not discuss class certification regarding his declaratory relief claim in his moving brief. Thus, it will not be addressed in this Opinion.
- 2 Defendants mainly take issue with the fact that Dr. Morwitz relies on this study to conclude that “virtually none” of Avis’s customers knew about the surcharge. This court agrees that if 15% of Avis’s customers did in fact know about the

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surcharge, the term "virtually none" would be an exaggeration. However, this study is not the sole basis upon which Dr. Morwitz forms her conclusion, and thus it is plausible that this study in conjunction with the other literature and data relied on by Dr. Morwitz supports her "virtually none" conclusion.

- 3 Because this Court has previously held that Plaintiff properly pleaded an unconscionable commercial practice under the NJCFA "[t]o the extent that Avis's alleged unconscionable conduct [was] premised on alleged omissions," (Docket No. 57, fn 3), this Court will apply the *Marcus* Court's "knowability" requirement to both unlawful practices alleged by Plaintiff.

End of Document

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Exhibit F

2016 WL 6652358

Only the Westlaw citation is currently available.

United States District Court,

D. New Jersey,

Camden Vicinage.

In re: Benicar (Olmesartan)

Products Liability Litigation.

Master Docket No. 15-2606 (RBK/JS)

Signed 11/08/2016

Filed 11/09/2016

OPINION**KUGLER**, United States District Judge

*1 Plaintiffs' submitted a request (Doc. No. 925) for leave to file a motion for partial summary judgement on the issue of general causation and accompanied it with fourteen (14) exhibits, either excerpts from defendants' depositions or documents produced by defendants. Plaintiffs assert the exhibits are defendants' admissions of general causation, which show that defendants' pharmaceuticals caused plaintiffs' complained of sprue-like enteropathy ["SLE"]. This opinion accompanies the order denying plaintiffs' request without prejudice (Doc. No. 938) and sets forth the reasons therefor.

I. Fact and Procedural Background

This Multidistrict Litigation ("MDL") involves approximately 1900 plaintiffs, who ingested defendants' olmesartan-containing prescription drugs¹ to alleviate hypertension. The named defendants are Daiichi Sankyo, Inc., Daiichi Sankyo Co., Ltd., Daiichi Sankyo U.S. Holdings, Inc., Forest Laboratories, LLC, Forest Laboratories, Inc., Forest Pharmaceuticals, Inc., and Forest Research Institute, Inc. The Daiichi defendants designed, manufactured and sold the drugs at issue.² For a time the Forest defendants marketed the drugs. Daiichi Sankyo, Inc. and Daiichi Sankyo U.S. Holdings, Inc. are U.S. companies. Daiichi Sankyo, Inc. is a wholly-owned subsidiary of Daiichi Sankyo U.S. Holdings, Inc. which operates as a holding company. Daiichi Sankyo Co., Ltd.

is the parent company of Daiichi Sankyo U.S. Holdings, Inc. Daiichi Sankyo, Inc. operates as the commercial home office and U.S. corporate headquarters of Daiichi Sankyo Co., Ltd., which is a Japanese corporation with its principal place of business in Japan. *See generally* Master Answer of Daiichi Defendants ¶¶ 20, 23-27, 30-31 [Doc. No. 82].

In order to put the Plaintiffs' request in context, the court's management plan initially focuses only on general and specific causation issues, that is, whether defendants' drugs caused the complained of SLE symptoms, which include nausea, vomiting, diarrhea and weight loss.

To date, plaintiffs have taken at least twenty (20) depositions of present and former Daiichi U.S. employees and eighteen (18) depositions of present and former Daiichi Japan employees. The first phase of fact discovery regarding causation issues was all but completed by 30 September 2016;³ the litigation has now entered the next phase with plaintiffs' causation expert reports due 30 November 2016, defendants' expert reports due 31 January 31, 2017, expert depositions to completed by 28 February 2017, and *Daubert* and summary judgment motions due by March 31, 2017. CMO No. 26. [Doc. No. 626]. The date for the *Daubert* hearing has not yet been set.⁴

*2 Turning to plaintiffs' request filed 13 October 2016 [Doc. 925], it comprises a summary of the 14 accompanying exhibits, which are excerpts of defendants' deposition testimony or defendant-produced documents, and characterizes them as admissions that defendants generally caused plaintiffs' injuries. Plaintiffs' request lacks not only an explanation as to how these summaries and excerpts constitute incontestable facts upon which to base a summary judgement motion but also any jurisprudential support that defendant alleged admissions during discovery in and of themselves properly substitute for expert testimony to demonstrate general causation.

Defendants argue that case law requires plaintiffs to offer admissible expert testimony on general causation because, in this case, linking the cause of each plaintiffs SLE injury to defendants' pharmaceuticals is beyond the ordinary understanding of a lay jury. Ds Response at 2. Defendants also argue that the excerpted testimony and documents are insufficient to unequivocally demonstrate that the

pharmaceuticals caused the complained of injury in each of plaintiff's cases. *Id.* at 3.

The issue is whether the deposition excerpts and internal documents proffered by plaintiffs substitute as expert testimony reliable and fit under *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) to sufficiently inform a jury that defendants' pharmaceuticals caused plaintiffs' SLE in these cases.

II. Legal Standard

Courts generally recognize that plaintiffs in products liability cases must offer admissible expert testimony regarding both general causation and specific causation. See, e.g., *In re Mirena IUD Products Liability Litigation*, ___ F. Supp.3d ___ (S.D.N.Y. 2016) 2016 WL 4059224 at *5, citing *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002; see *Rutigliano v. Valley Bus. Forms*, 929 F.Supp. 779, 783 (D.N.J. 1996), *aff'd sub nom. Valley Bus. Forms v. Graphic Fine Color, Inc.*, 119 F.3d 1577 (3d Cir. 1997) and further stating that "substantive law across all relevant jurisdictions holds (reference omitted) that 'where a causal link is beyond the knowledge or expertise of a lay jury, 'expert testimony is required to establish causation' (citations omitted)". *Id.*

Recently, the *Mirena* court found that, although there may be circumstances when defendants' admissions in a product liability case can substitute for expert testimony, those circumstances are "exceedingly rare". *In re Mirena* at *8. Expert testimony is generally required in product liability cases because it prevents the jury from engaging in speculation in determining the causal link between using or ingesting the product and the injuries complained of following that use. *Id.* at *5. Determining that causal link typically requires complex medical information beyond the knowledge, understanding, and experience of a lay juror. Expert testimony typically provides this link. See generally Christopher R.J. Pace, *Admitting and Excluding General Causation Expert Testimony: The Eleventh Circuit Construct*, 37 AM. J. TRIAL ADVOC. 47, 51-60 (2013) (comparing the probative value of various general causation methodologies used by experts to support their testimony as *Daubert* reliable).

Purported admissions offered as substitutes for expert testimony must be "clear, unambiguous, and concrete" and suffice to prove general causation without speculation. *Id.* at *8. "They can substitute for expert

testimony only when they serve the same purpose as expert testimony, that is, to provide the jury with a scientific, non-speculative basis to assess general causation." *Id.* at *12.

Also recently, a court in the Third Circuit analyzed an analogous issue—whether the plaintiffs were able to establish general causation with virtually no expert testimony, which had been excluded as inadmissible under *Daubert* and Federal Rule of Evidence (FRE) 702. *In re Zolof Products Liability Litigation*, ___ F. Supp.3d ___ (E.D. Pa. 2016) 2016 WL 1320799. There, plaintiffs found themselves precluded from offering new expert testimony on the issue of general causation—whether *Zolof* caused the complained of birth defects—and were left with arguing that other evidence established causation. Such other evidence included declarations by treating physicians of differential diagnoses, case reports by treating physicians of the occurrence of birth defects, defendants' internal documents including literature reviews and published studies relying on statistics about whether *Zolof* was the cause of the complained of birth defects, foreign language documents that contained a warning against pregnant women's ingestion of *Zolof*, and drafts of product documents. *Id.* at *9.

*3 The *Zolof* court found that, taken together, plaintiffs' potentially admissible evidence supported only an association between the drug at issue and the complained of birth defect and therefore presented only a possibility of general causation. *Id.* at *10. The court found that "plaintiffs have not produced sufficient admissible evidence from which a reasonable factfinder could determine, by a preponderance of the evidence, that [the drug at issue] could have caused Plaintiff's injuries." *Id.*

Mirena and *Zolof* resolve the issue raised by plaintiffs' request. Unless information characterized by plaintiffs as defendants' admissions provide to the jury evidence that is clear, unambiguous, and concrete and suffices to prove general causation without the jury's speculation as to complex medical issues, then such information does not substitute for *Daubert*-admissible expert testimony of general causation.

III. Discussion of Proffered Information by Plaintiffs

Each of the 14 exhibits will be reviewed for its sufficiency to substitute as expert testimony that demonstrates general causation without relying on a jury's speculation as to what the exhibit means.

Exhibit 1: 5 page excerpt (out of at least 461 pages) from the deposition of Crawford Parker, MD, defendants' Senior Director of Clinical Safety and Pharmacovigilance ("CSPV") in the United States.

Plaintiffs' request provides no specific reason for including Dr. Parker's testimony, nor contextualizes this excerpt within the deposition as a whole. Dr. Parker's testimony relates to certain documents that Dr. Parker provided to Dr. Peter Green, apparently a medical consultant to defendants, in advance of an unidentified meeting at which SLE adverse events were to be discussed. These documents included: a January 2009 review by defendants of celiac disease AE reports; the defendants knowledge of the 2012 Mayo Clinic publication⁵; the FDA request to Defendants to review SLE adverse events; and a September 2012 review by defendants of SLE adverse events.

Despite plaintiffs' repeated attempts, the excerpt shows that Dr. Parker expressly declined to characterize the information in one of defendants' ROADMAP clinical study as "an analysis". Dr. Parker's testimony does not suffice to inform in a clear, unambiguous, and concrete way and without jury speculation as to the complex medical issues involved in determining the mechanism by which olmesartan may generally cause the complained of injuries. This exhibit does not substitute for *Daubert*-admissible expert testimony of general causation.

Exhibit 2: 1 page excerpt (out of at least 165 pages) from the deposition of defendants' employee in Japan, Akinori Nishiwaki.

Plaintiffs' request states no specific reason for including Nishiwaki san's testimony or contextualizes this excerpt within his deposition as a whole nor was Nishiwaki san's role for defendants identified.

Plaintiffs' attorney read the following sentence from an unidentified document: "Before identifying olmesartan as a cause of villous atrophy, we, too, had considered 30 percent of our seronegative patients to have unclassified sprue". Nishiwaki san was then asked to confirm the presence of the word "cause" in the sentence, which he did.

That this one sentence included the word "cause" and that the deponent affirmed the presence of that word is not a clear, unambiguous, concrete, or sufficient demonstration of general causation.

**4 Exhibit 3. 5 page excerpt (out of at least 415 pages) from the deposition of Allen Feldman, MD, head of defendants' CSPV unit in the United States.*

Plaintiffs assert that Dr. Feldman "admitted that the only cause he could identify for the [symptoms] suffered by these patients was Olmesartan [emphasis added]." (Ps Letter Request at 4-5). When asked about the meaning of a statement in a Medwatch report⁶ (specifically whether the most likely explanation for patients' symptoms was olmesartan given their history of ingestion and dechallenges and positive rechallenges of the drug), Dr. Feldman replied: "The only cause given here [in the Medwatch report] is olmesartan". Feldman Dep. 285:24.

Dr. Feldman was only asked to confirm what a certain Medwatch report states; he was not asked as a medical professional to admit that olmesartan caused plaintiffs' symptoms. Dr. Feldman's deposition testimony is not clear, unambiguous, concrete or sufficient as to demonstrate general causation.

Exhibit 4: Email of 2 pages dated 26 March 2015, sent jointly from Ford Parker, MD, the same employee as in Exhibit 1, Ulf Stellmacher, director of defendants' CSPV unit in Europe, and Hideki Tagawa, associate manager of defendants' CSPV unit in Japan, to all employees in each of defendants' CSPV units (in the US, Japan and Europe).

Having the subject of "Coding and Expectedness of Sprue-Like Enteropathy for Olmesartan and Olmesartan Combination Products", the email states that the code "Syndrome SLE" was added as an expected reaction to the US Product Insert ("USPI") on 3 July 2013 and to defendants' Company Core Data Sheets ("CCDSs") in September 2013. The email provides recommendations to defendants' CSPV on how to determine expectedness⁷ because it is believed they may not understand SLE symptoms. To that end, the email identifies "Syndrome SLE" as including "nausea, vomiting and diarrhea, signs typical of olmesartan induced sprue-like enteropathy, such as weight loss." Exhibit 4, at ¶1. The apparent purpose here is to inform CSVP employees how Syndrome

SLE will be reported (presumably by clinicians) and how to code that information in periodic safety reports to regulatory agencies.

*5 The email states: “ ‘Syndrome sprue-like’ is currently the DSPD⁸ (the “Daichii Sankyo Pharmaceutical Development” functional unit) recommended term in MedDRA Version 16.1”⁹ and advises that a report coded as olmesartan-related intestinal villous atrophy should be handled as a sprue-like enteropathy report, in order to conform with the findings in the Mayo Clinic publication (Rubio-Tapio, *supra*) that first publicly reported that villous atrophy in olmesartan-takers was related to their SLE symptoms. Item 4 of the email recommends that, when a clear diagnosis of SLE is not reported (presumably by a clinician), symptoms of diarrhea, malabsorption, or weight loss should be coded not as SLE, but as separate reactions.

Although stating that there are signs typical of olmesartan induced sprue-like enteropathy, this exhibit expressly informs defendants' employees that these signs, when not accompanied by a clear diagnosis, cannot be reported as SLE. Since the exhibit on its face calls for a clinician's diagnosis before defendants will report olmesartan induced SLE, it cannot provide clear, unambiguous, and concrete proof of general causation. Without more, and in light of the entire email, the mere use by defendants of the term “olmesartan induced sprue-like enteropathy” does not suffice to inform a jury as to general causation.

Exhibit 5: Email from Dr. Ulf Stellmacher to Crawford Parker, MD, and Hideki Tagawa, dated to 16 Jan 2015, attaching a summary of the “3rd fatal SLE case we have just processed”. The attachment is a Power Point of 3 slides apparently prepared by Dr. Stellmacher, director of defendant's CSPV unit in Europe.

Slide 2 states that villous atrophy was found in a 70 year-old man living in France who had been taking Olmetec® or Alteis®¹⁰ for an unknown period and who had died. As defendant-manufactured equivalents to the pharmaceuticals issued here, the medications were for hypertension. The slide states that “Causality cannot be denied based on available information. Though diagnosis was not confirmed, this case represents SLE”.

This exhibit does not detail the causal link between the injuries complained of and the drugs at issue and cannot demonstrate general causation.

Exhibit 6: 8 page excerpt (out of at least 84 pages) from the deposition of Hideki Tagawa, associate manager of defendants' CSPV unit in Japan.

Tagawa san is apparently being asked to comment on the Power Point in Exhibit 5 above. He confirms that it states the cause of the death of a 70 year-old man in France was an olmesartan drug. Tagawa Dep. 58: 9 to 60: 20.

He is then asked to comment on an unidentified Power Point and on other unidentified documents, which leaves this court no point of reference from which to review independently to what Tagawa san is attesting to. Tagawa san confirms that the unidentified Power Point states: (1) based on reports of SLE in the U.S., a causal relationship between olmesartan-containing drugs and severe diarrhea could not be denied; and (2) Japanese and U.S. package inserts were modified to add diarrhea as a serious side effect following the U.S. reports. *Id.* at 69-70. He also confirms that he wrote an email stating that U.S. and Japanese reports indicated that chronic diarrhea improves when olmesartan is stopped in most cases. He states that what he wrote in that email is based on what defendants' medical advisors had told him. *Id.* at 83-84.

*6 Although Tagawa san affirms that he wrote certain content relating to SLE and confirms the statements set forth in the documents before him, he clearly indicates he is not an expert able to independently attest to general causation. This exhibit cannot demonstrate general causation.

Exhibit 7: 3 page excerpt (out of at least 173 pages) from the deposition of Yasushi Hasebe, head of defendants' CSVP unit in Japan.

Plaintiffs' request does not contextualize this excerpt within the deposition as a whole.

Hasebe san was asked: “You're not denying that the olmesartan was one of the factors causing the severe diarrhea, dehydration and hospitalizations described in this adverse report. You're not denying that, right?” Hasebe Dep. 127: 14-19. He answers, “Correct, I think that's one of the factors”. *Id.* at 127:21-22.

Inasmuch as Hasebe san's answer would lead to jury speculation as to what other factors caused the complained of injuries, the exhibit is not clear, unambiguous, specific or sufficient to demonstrate general causation.

Exhibit 8: 1 page excerpt (out of at least 152 pages) from the deposition of Mahmoud N. Ghazzi, M.D., Ph.D.

Plaintiffs' request states no specific reason for including Dr. Ghazzi's testimony or contextualizes this excerpt within the deposition as a whole nor was Dr. Ghazzi's role for defendants identified. Research from independent sources identifies Dr. Ghazzi as defendants' Global Head of Drug Development, as well as Head of Daiichi Sankyo Pharmaceutical Department in the U.S.

In response to questions about Deposition Exhibit No. 3068, which was neither provided nor summarized, and which the court, therefore, could not review, Dr. Ghazzi confirmed that, in May 2014, defendants were starting to arrange a meeting with key European opinion leaders (presumably in the medical and scientific fields) to understand the mechanism of olmesartan and its effects on patients. Ghazzi Dep. 152: 11-16. The only rational inference to be drawn from this evidence is that defendants' employees do not fully understand the cause of SLE. This excerpt cannot substitute for *Daubert*-reliable testimony as to general causation.

Exhibit 9: 2 page excerpt (out of at least 290 pages) from the deposition of Oliseyenum MacDonald Nwose, M.D., defendants' head of medical affairs and "responsible for the Olmesartan drugs", according to plaintiffs' letter request. Plaintiffs' request does not contextualize the excerpt within the deposition as a whole.

In response to the question whether it is more likely than not that olmesartan causes SLE and serious [gastrointestinal problems](#) in some patients, Dr. Nwose states there have been cases "where olmesartan has been associated with sprue-like [enteropathy](#)" (Nwose Dep. 289:8-14; 290:1-2) and adds that before forming a conclusion as to causation, he would have to "go back and review each of these cases individually". *Id.* at 290: 7-9.

Here, a possible medical expert eschews assigning the label of causation onto olmesartan for SLE symptoms until he

has reviewed each case himself. On its face, Dr. Nwose's testimony is no substitute for expert witness testimony.

Exhibit 10: 1 page excerpt (out of at least 151 pages) from the deposition of Anthony Corrado, Defendants' Director of Commercial Regulatory Affairs from 2011 to 2015.

*7 Plaintiffs' request does not contextualize this excerpt within the deposition as a whole.

Mr. Corrado answers "there is a probability" to the question whether defendants agree that some patients do suffer severe gastrointestinal side effects from taking olmesartan-containing drugs. Corrado Dep. 151: 10-15. Mr. Corrado's answer does not resolve the issue of general causation because there is no elimination of other agents possibly causing SLE symptoms in olmesartan patients. This exhibit is not clear, unambiguous, concrete or sufficient to demonstrate general causation.

Exhibit 11: 4 page excerpt (out of at least 147 pages) from the deposition of Diane Benezra-Kurshan, M.D.

Plaintiffs' request does not contextualize this excerpt within the deposition as a whole and appears to identify Dr. Benezra-Kurshan as that member of defendants' Label Review Committee who drafted proposed warning language to physicians regarding olmesartan use. The date of the proposed warning language is unidentified but after the publication of the Rubio-Tapio article, *supra*.

Dr. Benezra-Kurshan is asked about the meaning of her proposed drug label and its message to physicians. She answers that the label would read to physicians that olmesartan is probably causing the SLE and advises physicians to stop drug ingestion and the SLE symptoms may go away. Benezra-Kurshan Dep. 133:1-8. She adds that the proposed label would also indicate to physicians that, when the drug is stopped, and patients don't improve, then causes other than olmesartan ingestion should be investigated. *Id.* at 147:9-14.

Although this excerpt speaks to defendants' knowledge and response, after the Rubio-Tapio article, *supra*, to the occurrence of SLE symptoms in relation to olmesartan ingestion, it does not suffice as clear, unambiguous, and concrete demonstration of general causation.

Exhibit 12: 12 page excerpt (out of at least 178 pages) from the deposition of Makoto Mizuno, defendants' employee in Japan, who collaborated on the development of olmesartan. Mizuno san is asked: "Based on everything you've seen and the study that you were doing in your company with a team of people, you do agree that there is some number of people—we don't have to argue about how many—some people who do develop sprue-like enteropathy from taking olmesartan, correct?" Mizuno Dep. 177: 23 to 178: 5. He responds: "I think that some patients—among some patients who were taking olmesartan, there were some patients who developed sprue-like enteropathy". Id. at 178:8-12.

It is unclear why plaintiffs have proffered this exhibit as evidence of general causation since Mizuno san simply states there is a co-occurrence in some patients taking olmesartan with their experience of SLE. The exhibit is not clear, unambiguous, and specific evidence sufficient to demonstrate general causation.

Exhibit 13: 27 page excerpt (out of at least 364 pages) from the deposition of Jeffrey Warmke, Ph.D., defendants' witness under Federal Rule of Civil Procedure 30(b)(6).

Dr. Warmke attests that defendants received reports of the occurrence of villous atrophy, and/or gastroenteritis, or collagenous colitis—symptoms complained of in this litigation—in three patients participating in their clinical ROADMAP studies.¹¹ Warmke Dep. 327:21 to 331:3; 340:18 to 345:18; 348:6 to 349:1. He also attests that defendants' analysts documented that two of these occurrences had a causal relationship to the olmesartan ingestion. *Id.* at 345:6 to 19; 349:13 to 350:10.

***8** Although this exhibit may support specific causation if the patients Dr. Warmke discussed are also plaintiffs in this matter, it does not resolve the issue of the general causation of injuries complained of by all plaintiffs here. See generally RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL & EMOTIONAL HARM § 28 comment c (2010) ("The concepts of general causation and specific causation are widely accepted among courts confronting causation issues with toxic agents.").

Exhibit 14: 7 page excerpt (out of at least 137 pages) from the deposition of Dr. Katsuyoshi Chiba, defendants' employee in Japan.

Plaintiffs' request provides no specific reason for including Dr. Chiba's testimony or contextualizes this excerpt within the deposition as a whole nor identifies Dr. Chiba's role for defendants.

Particularly salient in Dr. Chiba's testimony in this exhibit are:

-“it is not possible to reproduce the results of the clinical studies by Mayo Clinic” (Dr. Chiba Deposition Transcript 59:7-8);

-“I think the best scenario would be that this will not be conducted by the non-clinical side” (referring to a non-clinical comparison test of olmesartan with other anti-hypertension drugs that also rely on the action of a TGF- β inhibitor, designed to determine whether all such hypertension drugs are linked to symptoms that plaintiffs complained of) (*Id.* at 64: 21-24);

-“ it wasn't a matter of proving or not [the relationship between olmesartan and SLE] but rather it was not possible for us to carry out any kind of nonclinical studies with — with—in — in a reliable manner” (*Id.* at 65: 16-19).

This exhibit appears to relate to whether defendants' choice not to conduct non-clinical tests indicated a belief that such tests would show a causal connection between olmesartan ingestion and SLE symptoms. Dr. Chiba's testimony confirms that, since such a test was not conducted, there can be no information pointing to general causation and therefore cannot demonstrate it.

Conclusion

None of the exhibits proffered by plaintiffs either singly or in combination evidences in a clear, unambiguous, and concrete way the mechanism by which the olmesartan-containing drugs at issue may generally cause the complained of injuries. No exhibit or combination can resolve the inevitable jury speculation as to the complex biochemical, biological, and epidemiological information that underpins the general causation question here.

Consequently, this court declines to find or characterize whether any of the proffered exhibits is an admission by defendants under Federal Rule of Evidence 801(d) (2).

In re: Benicar (Olmesartan) Products Liability Litigation, Slip Copy (2016)

2016 WL 6652358

Accordingly, for all the reasons discussed above, plaintiff's Request to File Summary Judgement Motion on Submitted Exhibits has been DENIED in Doc. No. 938.

Dated: 11/8/2016.

All Citations

Slip Copy, 2016 WL 6652358

Footnotes

- 1 These drugs are Benicar®, BenicarHCT®, Azor®, and Tribenzor®; they are collectively referred to herein as "olmesartan".
- 2 The Court will collectively refer to all the Daiichi party defendants as "Daiichi."
- 3 The Court granted plaintiffs leave to take some additional depositions after September 30, 2016, but cautioned this would not extend any other scheduling deadline. See September 1, 2016 Order at 3. [Doc. No. 874].
- 4 In addition to the cases in this MDL, approximately 73 related cases are consolidated in New Jersey State Court as Multicounty Litigation ("MCL"). Discovery in the federal MDL and state MCL has been coordinated. The Court anticipates a joint Daubert-type hearing will be held in the spring or summer of 2017. The state equivalent to Daubert is *Kemp ex rel. Wright v. State*, 174 N.J. 412 (2002).
- 5 A. Rubio-Tapio *et al.*, *Severe Spruelike Enteropathy Associated with Olmesartan*, MAYO CLIN. PROC. 87(8), 732:738 (2012).
- 6 A MedWatch report is a voluntary report to the U.S. Federal Drug Administration (FDA) of an adverse event or undesirable effect associated with using a medical product, including pharmaceuticals and medical devices. The report can be prepared on a one-page FDA form or done via the telephone by health care professionals, patients, and consumers.
- 7 From a regulatory perspective and in relation to the periodic safety reports (titled in the U.S. as Development Safety Update Report ("DSURs")) provided to a national regulatory agency by the manufacturer of a drug either under development or that has been marketed and under further study, the term "expectedness" relates to whether a physiological reaction is a statistically expected side effect of the pharmaceutical. *Guidance for Industry. E2F Development Safety Report*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. FOOD AND DRUG ADMINISTRATION, prepared by INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE (ICH), August 2011 (containing nonbinding recommendations), <http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073109.pdf>.
When categorized as expected, a physiological reaction to drug ingestion must be clearly listed in the Reference Safety Information (RSI) of the DSUR provided by the drug manufacturer to the regulatory agency. *Id.* at 11, 14 and 23.
- 8 Defendants' unit that does pharmaceutical research, development, and marketing primarily in the U.S.
- 9 Developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the Medical Dictionary for Regulatory Activities ("MedDRA") provides a globally standardized terminology to regulatory agencies (including the U.S. Food and Drug Administration, the European Medical Agency, and the Japanese Pharmaceutical and Medical Device Agency), pharmaceutical companies, clinicians, and translators, <http://www.medra.org>.
- 10 Olmetec® is a trademark registered in Japan to Daiichi Sankyo. Alteis™ is a brand name used by Daiichi Sankyo. These marks identify an olmesartan formulation equivalent to Benicar® and are used to market that in France. <http://mpkb.org/home/mp/olmesartan/buying>
- 11 Defendants conducted their own clinical studies of the olmesartan-containing drugs, which were designed to determine a reduction in the level of albumin in a patient's urine. Inasmuch as such albumin is a biochemical indicator of kidney disease due to hypertension, Defendants' ROADMAP tests were to some extent analyzing the statistical effectiveness of olmesartan ingestion on hypertension.

End of Document

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